

REMARKS

Based on the above amendments and the following remarks, this application is deemed to be in condition for allowance and action to that end is respectfully requested.

Disposition of Claims in Office Action

Claims 1- 18 are pending in the application

Claims 1- 18 stand rejected.

Summary of Amendments to the Claims

Claims 1-18 remain pending in the application.

Claims 1 and 13 have been amended. Claims 19- 35 are new.

Applicant believes that no new matter has been added.

Response to Objections to the Specification

The Examiner objected to the specification because of a typographical error in paragraph [0019] on page 5, line 8 of the specification. Applicant has corrected the typographical error. Accordingly, Applicant respectfully submits that this objection has been overcome and withdrawal thereof is respectfully requested.

Objections to Trademarks and Their Use

The Examiner objected to Applicant's use of the trademark "SPHEREX®" in the application. Applicant has amended the specification to address this objection. Accordingly, Applicant respectfully submits that this objection has been overcome and withdrawal thereof is respectfully requested.

Response to Claim Rejection - 35 U.S.C. § 102(b)

The Examiner rejected Claims 1-7, 9, 10, 12-15 and 17-18 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,858,398 to Cho (Cho I). The Examiner also rejected Claims 1-6 and 8-18 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,656,289 to Cho et al. (Cho II). The Examiner further rejected Claims 1-5, 9, 10, 12-15 and 17-18 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,615,885 to Nakagame et al. (Nakagame). Applicant respectfully disagrees.

For a claimed invention to be anticipated by a single prior art reference pursuant to 35 U.S.C. § 102(b), the reference must teach every aspect of the claimed invention either explicitly or impliedly. In other words, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *See Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicant respectfully submits that Cho I fails to disclose, either expressly or inherently, each and every element of Claims 1-7, 9, 10, 12-15 and 17-18, Cho II fails to disclose, either expressly or inherently, each and every element of Claims 1-6 and 8-18 and Nakagame fails to disclose, either expressly or inherently, each and every element of Claims 1-5, 9, 10, 12-15 and 17-18.

Applicant has amended the claims to more particularly define the invention. Specifically, Applicant describes and claims an exemplary composition comprising a

core containing a pharmaceutically active agent wherein the core is encapsulated with a membrane comprising esterified C₁₂-C₁₈ fatty acids to form a pro-micelle wherein the concentration of fatty acids in the composition is less than 15 weight %. According to Applicant's specification:

The present invention provides pharmaceutical compositions comprising a pharmaceutically active agent encapsulated within a membrane of esterified C₁₂-C₁₈ fatty acids, which is further optionally encapsulated within a gelatin capsule. Fatty acids are present in the composition in a total concentration of less than 15 weight % so that the composition is in the form of a "pro-micelle." The term pro-micelle as used herein means a composition having a concentration of C₁₂-C₁₈ fatty acids that is insufficient to form a micelle, but that which is capable of forming a micelle upon exposure to fatty acids in the digestive system of a mammal.

(Paragraph [0018], p. 4)

None of Cho I, Cho II or Nakagame discloses compositions that form pro-micelles.

Cho I discloses compositions comprising a microparticle of active agent, phospholipid and surfactant wherein the microparticle is suspended in a micelle. Accordingly, Cho I does not teach pro-micelle formation.

Cho II discloses compositions of biologically active material which comprise a water-in-oil microemulsion, wherein the hydrophilic phase of the microemulsion comprises the biologically active material and the hydrophobic phase comprises chylomicra or material capable of forming chylomicra in the intestinal mucosa after administration. Accordingly, Cho II does not teach pro-micelle formation.

Finally, Nakagame is directed to liposome preparation comprising urokinase and higher fatty acids, a polyalkylene glycol and calcium. Accordingly, Nakagame does not teach pro-micelle formation.

Based on the foregoing, Applicant respectfully submits that the claims at issue are not anticipated by the applied references because the references do not meet the claim limitations. Accordingly, the rejection under 35 U.S.C. 102(b) is overcome and withdrawal thereof is respectfully requested.

Response to Claim Rejections - 35 U.S.C. § 103

The Examiner rejected Claims 1-18 under 35 U.S.C. § 103 as being unpatentable over Cho I in view of Cho II.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on an applicant's disclosure in the specification. *See In re Vaech*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Applicant respectfully submits that the combination of Cho I in view of Cho II (whether or not they can be properly combined), fails to teach or suggest, either expressly or inherently, all the limitations of the claims. That is, even if combined, the combination

of Cho I in view of Cho II would not meet the claims because the proposed combination lacks all the limitations of the claimed invention. As discussed above in the section above, unlike the claimed invention, neither Cho I or Cho II discloses compositions that form pro-micelles. Therefore, Applicant respectfully submits that the claimed invention is unobvious over the applied prior art. Accordingly, the Examiner's rejection under 35 U.S.C. § 103(a) is overcome and withdrawal thereof is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance and accordingly, allowance of the application is respectfully requested.

Should the Examiner require or consider it advisable that the specification, claims and/or drawings be further amended or corrected in formal respects in order to place the case in condition for final allowance, then it is respectfully requested that such amendment or correction be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, the Examiner is invited to telephone the undersigned.

The Commissioner is authorized to charge all required fees, including any extension and excess claim fees, or credit any overpayment to Deposit Account 06-0923. Applicant claims small entity status. See 37 C.F.R. 1.27.

Respectfully submitted for Applicant,



Louis S. Sorell (Reg. No. 32,439)
GOODWIN PROCTER LLP
599 Lexington Avenue
New York, NY 10022
(212) 459-7421